

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Efficiency of Probiotic on Helicobacter Pylori Eradication, a Retrospective Parallel Group Double-Blind, Placebo-Controlled Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of effect of probiotic on H. pylori eradication

Design

A parallel double-blind placebo-controlled trial, using computer package which generated random numbers, simple random allocation rule, with 100 participants.

Settings and conduct

Double-blind placebo-controlled trial, using laboratory tests for evaluation of eradication, using symptoms questionnaire.

Participants/Inclusion and exclusion criteria

Adult patients who their infection confirmed through histology, serum anti-H. pylori IgG, or stool antigen tests. The exclusion criteria were; taking antibiotics, bismuth component, proton pump inhibitor (PPI), and H2Blocker in the recent 2-3 months, pregnant women, patients with previous history of GI surgery, having concurrent severe disease during the time of experiment

Intervention groups

Treatment group should take probiotic, despite control group with taking placebo for two weeks. Both of them take this regimen; Omeprazole 20mg + Amoxicillin 1 gr + clarithromycin 500 mg twice daily, and with 6 weeks followed up study.

Main outcome variables

Finding new strategy or supplementation for eradication of this infection due to prevalence of drug therapy resistance and related side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181015041349N1**

Registration date: **2019-02-09, 1397/11/20**

Registration timing: **retrospective**

Last update: **2019-02-09, 1397/11/20**

Update count: **0**

Registration date

2019-02-09, 1397/11/20

Registrant information

Name

Seyed Jalil Masoumi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 2771

Email address

ebrahimiv@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-21, 1394/02/31

Expected recruitment end date

2015-09-20, 1394/06/29

Actual recruitment start date

2015-06-21, 1394/03/31

Actual recruitment end date

2015-11-05, 1394/08/14

Trial completion date

2015-11-05, 1394/08/14

Scientific title

The Efficiency of Probiotic on Helicobacter Pylori Eradication, a Retrospective Parallel Group Double-Blind, Placebo-Controlled Randomized Clinical Trial

Public title

The Efficiency of Probiotic on Helicobacter Pylori Eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with aged 18-63 years participants who their contamination were confirmed through histology, serum anti-H. pylori IgG, or stool antigen tests.

Exclusion criteria:
The exclusion criteria were taking antibiotics, bismuth component, proton pump inhibitor (PPI), and H2Blocker in the recent 2-3 months. Pregnant women as well as patients with previous history of GI surgery or having concurrent severe disease during the time of experiment also been excluded.

Age
From **18 years** old to **63 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **100**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was conducted using computer package which generated random numbers and group allocation was as well done by simple random allocation rule.
Couples were randomly allocated into either probiotic (50 subjects, group A) or placebo (50 subjects, group B).

Blinding (investigator's opinion)
Double blinded

Blinding description
-

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz university of medical science

Street address
Zand avenue

City
Shiraz

Province
Fars

Postal code
7376116678

Approval date
2015-04-18, 1394/01/29

Ethics committee reference number
3901

Health conditions studied

1

Description of health condition studied
Effect of Probiotic on Eradication of H.pylori Infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Eradication of H.pylori Infection

Timepoint
before intervention and 8 weeks later (after follow-up)

Method of measurement
histology, serum anti-H. pylori IgG, or stool antigen tests.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Probiotic (saccharomyces boulardii (250 mg, 1010 viable cells/g).Two weeks, twice per day.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Nemazee hospital

Full name of responsible person
Seyed Jalil Masoimi

Street address
Namazee Hospital- Zand Ave.- Namazee Square

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Shiraz

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7134874853

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

3901

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Jalil Masoumi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyed Jalil Masoumi

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Ebrahimi

Position

Ph.D biostatistic student

Latest degree

Master

Other areas of specialty/work

Biostatistics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments